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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,106	04/19/2004	Gopi M. Venkatesh	EURA-008/00US 307853-2228	1448

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	**PAPER NUMBER**
1618	

NOTIFICATION DATE	DELIVERY MODE
10/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/827,106	**Applicant(s)** VENKATESH ET AL.	
	Examiner JAGADISHWAR R. SAMALA	**Art Unit** 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 August 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *1* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *1-15*.
   Claim(s) withdrawn from consideration: *16-24*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: The current proposed amendment requires further search and consideration. As the applicant has now limited the scope of the instant claim 1 reciting sugar alcohol or a saccharide, the instantly claimed composition is now drawn to a single embodiment with respect to the recited step (a), rather than as a rapid dispersing microgranules comprising of. As such, further search and consideration are needed. Therefore, the proposed amendment will not entered.

Applicant also argues that Gowan fails to disclose any information regarding friability or levels of fines for the drug particles. This argument is not persuasive since Gowan teaches that the dosage form has a size, shape, weight and hardness that allows for it to be introduced into the oral cavity and placed on the tongue, so as to rapidly disintegrate. The particle size of the coated particles is generally less than 150 microns and larger particle sizes are avoided. The components of the dosage form are then dry mixed to form a uniform powder blend, then compressed into a mass having the desired shape and hardness using conventional compression tableting techniques (col. 7). Applicant argues that Gowan fails to disclose excipients (disintegrants) such as crospovidone, fails to teach or suggest the RDM of the claimed invention. This argument is not persuasive since Gowan does teach coated granulated particle containing 5 to about 90 weight percent of the particle, with the reminder being the binder or filler such as polyvinyl pyrrolidone (crospovidone), HPMC, HPC and other pharmaceutically acceptable saccharides and microcrystalline cellulose (col. 5 lines 40-52).

Applicant argues that Ohta fails to disclose any coating-taste masking or otherwise on the drug containing granule. This argument is not persuasive because this reference is combined for its teachings of knowledge in the art of tablet comprising sugar alcohol or saccharide having an average particle diameter of not more than 30 microns, an active ingredient, and a disintegrant such as crosspovidone, crosscarmellose sodium. Further, Ohta teaches that the tablet can be obtained by compressing and tableting after granulating a mixed powdered component comprising sugar alcohol or saccharide having an average particle diameter of not more than 30 microns ground by means of a hammer mill or a jet mill or the like, an active ingredient and a disintegrant (0017). A wet granulation method using purified water, ethanol or the like can be preferably used. Applicant argues that none of the references disclose the said microgranule exhibiting not more than 15% fines (passing through 140 mesh screen) when tested in accordance with the procedure for friability test. This argument is not persuasive since Gowan teaches that coated acetaminophen particles passed through a 30 mesh screen and components are compressed into tablets having hardness less than 1.0 Kp result in a dosage form exhibiting high friability. Applicant argues that the examiner has improperly used hindsight knowledge of Applicant's invention in proposing the asserted combination of the cited references. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971)